



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,552	01/23/2004	Dusan Hesoun	SYN-0037	3211

38427 7590 03/09/2005

MARK R. BUSCHER
P.O. BOX 161
CATHARPIN, VA 20143

EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,552

Applicant(s)

HESOUN ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Application/Control Number:
10/762,552
Art Unit: 1626

Page 2

Claims 1-33 are pending in this application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims as not written in proper US format. They are drawn to a process, comprising contacting a formula, etc. with no identifiable product. Applicant should note that the process of making a compound is not a utility under 35 USC 101. The product must have an asserted utility or well-established utility. Since ondansetron has well-established utilities, by making claim 1 depend from claim 31 the rejection would be overcome. However, the intermediate compound of claim 1 must be identified in both claims 1 and 31. Also, the product is required to class and subclass claims 1-15.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Application/Control Number:
10/762,552
Art Unit: 1626

Page 3

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-15, 18, 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reason set forth above claims 1-15 are indefinite.

Claim 18 recites "imidazole compound is provided in said reaction mixture substantially simultaneously with the formation of said reaction mixture." It is not clear what applicant is claiming. It is not clear how "simultaneously" could be "substantially" nor clear how the imidazole is "provided". By deleting the claim the rejection would be overcome.

Claim 30 is written in functional language and therefore, broader than the enabling disclosure. For example, the claim recites "converting" in line 1. The claim must recite how one of ordinary skill in the art would perform the "converting". The claims must recite the reagents, the reaction times, pH, and reaction conditions that are applicable in the step. Applicant may not claim all applicable processes of "converting" in the instant invention, known and yet to be developed. Applicant must claim only the "converting" process that embodies applicant's invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number:
10/762,552
Art Unit: 1626

Page 4

Claims 1-6, 10-12, 15-18, 24, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Juping et al., CN 1110970A.

Juping et al., disclose the process of making compounds of formula (I) comprising reaction of compound II in acetic acid followed by addition of paraformaldehyde and dimethylamine or its HCL salt.

Claims 1-23, 25-29, 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Coates et al., Us 4,695,578.

Coates et al., disclose a process of making compounds of formula (I) comprising reaction of a compound II of formula with a compound of formula (III): process A, column 6, line 27 to column 7, line 30. Compounds of formula II are prepared from compounds of formula IV as shown in column 9, line 63 to column 10, line 24. The solvents include water, esters, acetic, ketones, amides, etc., and the temperature is from 20-150°C. In preferred embodiments, applicant claims various time-gaps before adding methyl-imidazole to the reaction mixture. There is no evidence that the reactions of Coates et al., has no such time gaps since the reaction is a 2-step process as is instantly claimed. Therefore, the Examiner assumed there are such time gaps absent a showing to the contrary.

Claim 30 is rejected under 35 U.S.C. 102(b) as being anticipated by Jichang et al., CN 1105994A.

Jichang et al., disclose the process of making compounds of formula (I) comprising reaction of compound II with ion-exchange resin, paraformaldehyde and dimethylamine HCL

Application/Control Number:
10/762,552
Art Unit: 1626

Page 5

salt. The compound of formula (I) is then reacted with concentrated HCL in isopropanol to make the HCL salt hydrate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 6-8, are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, US 4,480,124.

Applicant claims a process of making compounds of formula (1) comprising reaction of a compound II of formula with formaldehyde, water-binding agent, non-aqueous polar solvent and diethylamide compound of formula (3). The reaction product is then reacted with compound of formula (5). In preferred embodiments, the solvents include water, esters, acetic, ketones, amides, etc., and the temperature is from 50-150°C. Applicant also claims various time gaps before adding methyl-imidazole to the reaction mixture.

Determination of the scope and content of the prior art (MPEP 2141.01)

Coates et al., teach a process of making compounds of formula (I) comprising reaction of a compound II of formula with a compound of formula (III): process A, column 6, line 27 to column 7, line 30. Compounds of formula II are prepared from compounds of formula IV as shown in column 9, line 63 to column 10, line 24. The solvents include water, esters, acetic, ketones, amides, etc., and the temperature is from 20-150°C.

Application/Control Number:
10/762,552
Art Unit: 1626

Page 6

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Coates et al., is that applicant is claiming various time-gaps before adding methyl-imidazole to the reaction mixture while Coates et al., do not teach the time-gaps.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

There is no evidence that the reactions of Coates et al., has no such time-gaps since the reaction is a 2-step process as is instantly claimed. Therefore, the Examiner assumed there are such time-gaps absent a showing to the contrary. Also, the various time-gaps are obvious modifications available to the special preference of an artisan. They are mere optimization of variables, which are not patentable absent unexpected result due to each variable, which is different in kind and not merely in degree from that of the prior art. *In re Aller*, 22 F.2d 454, 105 USPQ 233 (CCPA, 1955). Therefore, the instant invention is prima facie obvious from the teaching of Coates et al. One of ordinary skill in the art would have been known to claim the time-gaps at the time the invention was made. The motivation is to maximize the production of product.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD., JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Application/Control Number:
10/762,552
Art Unit: 1626

Page 7

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read 'Solola', with a stylized flourish at the beginning.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

March 5, 2005